IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	)	C. A. No. 06-222 (JJF)

WYETH'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE IMPAX'S UNENFORCEABILITY AND UNCLEAN HANDS AFFIRMATIVE DEFENSES UNDER FED. R. CIV. P. 12(f), AND TO DISMISS IMPAX'S UNENFORCEABILITY COUNTERCLAIMS UNDER FED. R. CIV. P. 12(b)(6)

MORRIS, NICHOLS, ARSHT &
TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

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INTRODUCTION

Recognizing that its original answer and counterclaims asserting "unclean hands" and "unenforceability" were insufficiently pled to withstand Wyeth's motion, Impax now seeks to recast its pleadings as a patent misuse allegation. But Impax did not make any such allegation in its pleadings. More importantly, Impax's Opposition demonstrates that this new allegation has no legal or factual basis.

At the outset, the law recognizes a presumption that the assertion of a duly granted patent is made in good faith. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998). Further, Congress has specifically established that certain activities do not constitute patent misuse. 35 U.S.C. § 271(d). One of those activities is seeking enforcement of patent rights against infringement. 35 U.S.C. § 271(d)(3). *See Virginia Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997); *accord C.R. Bard, Inc.*, 157 F.3d at 1373. Neither Impax's pleadings nor its Opposition provide a basis for concluding that the safe harbor provisions of § 271(d) should not dispose of Impax's patent misuse allegation. The law does not permit conclusory allegations of patent misuse to constitute either a defense or a claim upon which relief could be granted. But that is all Impax has done here.

In essence, Impax's patent misuse allegation is that Wyeth filed this lawsuit in bad faith knowing that all of the patent claims require an ingredient, microcrystalline cellulose ("MCC"), and that Impax's formulation does not include this ingredient. Impax points to prior litigation between Wyeth and Teva in the District of New Jersey. According to Impax, after a Markman ruling where the New Jersey court construed every patent claim as requiring MCC, Wyeth immediately settled the lawsuit. (Opp., D.I. 14, at 7). This simply is incorrect. The Markman ruling was rendered September 6, 2005.

Notwithstanding that ruling, the parties proceeded towards trial. In mid-October, 2005, on the eve of trial, after summary judgment motions had been both briefed and argued, the parties reached a settlement. As part of that settlement, the Markman ruling was vacated. It has no effect.

The important point for the present motion is that although Impax did not plead patent misuse in its Answer, even if it had, that claim would fail, as a matter of law, because it is not patent misuse to settle a prior litigation. Nor is it patent misuse for a district court to vacate its own Markman ruling, or for Wyeth to assert infringement against a defendant whose sole defense is that its formulation contains an ingredient, MCC, that is not recited in several of the asserted claims. And it is not patent misuse to file a patent infringement action that is presumptively in good faith. Impax's naked allegations are insufficient as a matter of law to withstand Wyeth's motion to strike and dismiss for failure to state a claim.

Lastly, Impax uses its opposition as an opportunity to prematurely argue its erroneous claim construction that MCC is a required element of the claims, focusing on isolated portions of the patent specification and claim 1 of the '171 patent, which explicitly recites the ingredient MCC. (Opp., D.I. 14, at 6). Although the Court need not delve into claim construction at this time, suffice it to say that Impax simply ignores the plain language of other claims.[1] For example, Impax ignores independent method claim 20 of the '171 patent which is directed to a method that requires, among other things, the administration of an "encapsulated, extended release formulation . . ., said formulation

[1] Impax also ignores the fact that, even under its improper claim construction, it infringes under the doctrine of equivalents as it has merely replaced MCC with a substantial equivalent.

containing venlafaxine hydrochloride as the active ingredient." Unlike claim 1 which Impax quotes, there is no reference to MCC in claim 20. Impax's sole basis for noninfringement of claim 20 is its reliance on an ingredient that does not appear in, and is not required by, the claim. The doctrine of patent misuse cannot apply when the use of Impax's formulation literally falls within the language of at least this claim. Impax's clearly erroneous claim construction arguments cannot form the basis for a patent misuse defense.

ARGUMENT

A. Impax's Unclean Hands Defense and Unenforceability Counterclaims Are Insufficiently Pled

Impax essentially concedes that it provided no factual basis in its Answer and Counterclaim for its unclean hands defense or unenforceability counterclaims. Instead, Impax goes outside the pleadings to argue a new patent misuse defense that it never asserted. (Opp., D.I. 14, at 3-4). It is well-established, however, that in considering the sufficiency of a pleading, the Court may only review its well-pled allegations. *ALA, Inc. v. CCAir, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994); *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). Extraneous arguments made in defense of a motion are simply not relevant. *Id.*

Impax purports to rely on *McKesson Info. Solutions, LLC v. Trizetto Group, Inc.*, No. Civ. 04-1258-SLR, 2005 WL 914776 (D. Del. Apr. 20, 2005) to support the adequacy of its pleadings. Impax states that "[t]his Court found the pleading [of patent misuse by the defendant in *McKesson*] sufficient, even though there is no indication that the pleading in question had the detailed factual allegations to support a patent misuse defense that are present in Impax's Answer at issue here." (Opp., D.I. 14, at 13.)

Contrary to Impax's characterization, however, Trizetto's pleading was replete with facts alleging that the patentee actually knew that the patent at issue was invalid and unenforceable at the time the lawsuit was filed. Indeed, the inadequacy of Impax's pleadings in this case is underscored by the marked contrast between Trizetto's pleading in *McKesson* and Impax's pleading here.

For example, Trizetto alleged that an employee of McKesson's predecessor in essence admitted in a Harvard MBA case study review that McKesson's invention was trivial, and appended the case study to its Opposition. (Opp., D.I. 14, Ex. 2 at 2 and Exhibit A.) Trizetto further cited in its pleading other publications, admissions, and specific prior art, along with specific allegations based on those sources tending to show that the plaintiff indeed was aware of the inadequacy of its patent. Impax's citation of *McKesson* provides a contrasting mirror that reflects the inadequacy of Impax's own pleading.

As Wyeth's opening brief makes clear, the law does not permit conclusory allegations of enforceability or unclean hands to stand as either defenses or counterclaims. Patent misuse is no exception. *See, e.g.*, *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, No. 04 Civ. 1966 (DLC), 2004 WL 1872707, at *1 (S.D.N.Y. Aug. 19, 2004) (striking and dismissing defendant's patent misuse defenses and counterclaims, noting that "[t]he defendants merely parrot the elements of a claim for patent misuse, without alleging even general facts to support that claim. Conclusory references to an "anti-competitive effect" and "improper restraint on competition" contained in the defendants' pleadings are not sufficient to give Takeda notice of the misconduct alleged."); *Aktiebolag v. Genpharm Inc.*, No. 98 Civ. 3657 (BSJ), 2000 WL

257119, at *2 (S.D.N.Y. Mar. 8, 2000) (striking patent misuse defense, noting that "Genpharm offers nothing more than conclusory allegations which provide no factual basis for this defense-leaving the plaintiffs utterly without notice of the misconduct alleged."); *Advanced Cardiovascular Sys., Inc. v. SciMed Sys. Inc.*, 40 U.S.P.Q.2d 1291, 1294 (N.D. Cal. 1996) (dismissing patent misuse defense as insufficiently pled, noting that "[g]iven the specific exceptions to patent misuse provided by Congress [in 35 U.S.C. § 271(d)], defendant must plead more than a conclusory allegation of patent misuse in order to provide fair notice of the nature of the defense.").

Impax's unclean hands defense should be stricken and its unenforceability counterclaims dismissed because Impax's *pleading* plainly does not satisfy the requirements of Rules 8 or 9(b). Impax's new unpled patent misuse arguments cannot fix that deficiency.

B. In any Event, Impax's Unclean Hands Defense and Unenforceability Counterclaims Should Be Stricken Because Wyeth's Enforcement of its Patents Against Impax Cannot Itself Support an Allegation of Patent Misuse

Patent infringement suits are presumptively brought in good faith. As the Federal Circuit emphasized in *C.R. Bard,* 157 F.3d at 1369:

> The law recognizes a presumption that the assertion of a duly granted patent is made in good faith, *see Virtue v. Creamery Package Mfg. Co.,* 227 U.S. 8, 37-38, 33 S. Ct. 202, 57 L. Ed. 393 (1913); this presumption is overcome only by affirmative evidence of bad faith. *See* [*Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* (*PRE*) 508 U.S. 49, 60 (1993).]

And this presumption of good faith can be rebutted only by clear and convincing evidence. *Handgards, Inc. v. Ethicon, Inc.,* 601 F.2d 986, 996 (9th Cir. 1979).

To support an allegation of patent misuse, an alleged infringer must show that the patentee impermissibly broadened the scope of the patent grant with anticompetitive effect. *See, e.g., Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1002 (Fed. Cir. 1986). Notably, patent misuse does not include a general notion of "wrongful" use and is not an "open-ended pitfall for patent-supported commerce." *C.R. Bard,* 157 F.3d at 1373. Indeed, "in application [the patent misuse doctrine] has largely been confined to a handful of specific practices." *Id.* (*quoting USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 510 (7th Cir. 1982)); *see also* 6 Donald S. Chisum, *Chisum on Patents* § 19.04[3] (Matthew Bender & Co., Inc. 2005) (1978). Such specific practices do not include commercial restrictions reasonably within the patent grant. As the Federal Circuit has made clear,"[i]n the cases in which the [competitive] restriction is reasonably within the patent grant, the patent misuse defense can never succeed." *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004).

Under 35 U.S.C. § 271(d), a patent owner cannot be guilty of misuse simply by reason of seeking to enforce his or her patent:

> No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . (3) sought to enforce his patent rights against infringement or contributory infringement . . . .

35 U.S.C. § 271(d); *see also Advanced Cardiovascular Sys., Inc. v. Medtronic Inc.*, 41 U.S.P.Q.2d 1770, 1775 (N.D. Cal. 1996) (striking patent misuse defense, noting that "[u]nder 35 U.S.C. § 271(d), a patent owner cannot be denied relief or found guilty of misuse simply by reason of seeking to enforce his or her patent."). Nothing in Impax's pleadings or Opposition provide a basis for concluding that the safe harbor provisions of § 271(d) should not apply here.

In *Tristrata Tech. Inc. v. Neoteric Cosmetics, Inc.*, No. Civ. 96-227-JJF (D. Del. Sept. 30, 1997) (Farnan, J.) [Ex. 1], this court focused on the safe harbor provisions of § 271(d) in granting plaintiff's motion to dismiss the defendant's counterclaim of patent misuse as "insufficient and conclusory." In so holding, the court noted that:

> In examining [the defendant] Neoteric's allegations of patent misuse in light of the provisions of Section 271(d), the Court concludes that a number of Neoteric's allegations of patent misuse are within the safe harbor provisions of that section. Subsections (2) and (3) expressly encompass a patent owners license activities and enforcement activities. Indeed, in discussing Section 271(d), the Supreme Court stated that "[t]his provision plainly means that the patentee may bring suit without fear that doing so will be regarded as an unlawful attempt to suppress competition." *See Dawson* [*Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980)] at 201 . . . . ***To the extent that Neoteric contends that certain licensing and enforcement activities were improper and thus, not within the protection of Section 271(d), the Court finds Neoteric's allegations to be insufficient and conclusory***. Indeed, Neoteric has not alleged any facts that would lead the Court to conclude that TriStata's activities fall outside the safe harbor provisions.

Slip Op. at 8 (first alteration in original) (emphasis added).

Other than unfounded, conclusory allegations of bad faith, Impax's patent misuse defense simply rests on Wyeth having filed this lawsuit.[2] As a matter of law, this is insufficient to support a defense of patent misuse.

[2] Although not at issue in the pending motion, Impax's "facts" concerning Effexor® and Effexor® XR, Wyeth's immediate release and extended release formulation of venlafaxine hydrochloride, are simply incorrect. (Opp., D.I. 14, at 4). While alleging that Wyeth engaged in a "massive marketing campaign" to shift sales from Effexor® to Effexor® XR, Impax fails to mention that U.S. sales of Effexor® plateaued several years after launch at about $225 million per year; that Effexor® XR was launched after the sales of Effexor® plateaued; and that sales of Effexor® XR have continued to rise since its November 1997 launch, with annual U.S. sales today exceeding $2 billion.

C. Impax's Spurious Reliance on a Vacated Markman Order and the Settlement of a Prior Litigation Cannot Support Its Allegations of Patent Misuse

Impax's only additional allegation to support its new patent misuse defense, beyond the mere fact that Wyeth has asserted its patent rights, is that Wyeth purportedly knows that Impax's formulation contains MCC, and that "the claims of its patents require [MCC], because the District of New Jersey had recently construed the claims of the same three patents as requiring that ingredient." (Opp., D.I. 14, at 11). Impax further alleges in its Opposition that, after the New Jersey court Markman ruling, Wyeth immediately settled this lawsuit. (Opp., D.I. 14, at 7).

However, the New Jersey litigation involving a different defendant, Teva, settled in mid-October, 2005, well after the September 6, 2005 Markman ruling. The settlement came on the eve of trial, after summary judgment motions had been briefed and argued, but not decided. As part of the settlement, Teva's invalidity and unenforceability counterclaims were dismissed with prejudice, and Teva was enjoined from marketing its generic product except as provided for in a license agreement that was part of the settlement [Ex. 2, Dismissal Order dated January 12, 2006]. The New Jersey district court also issued an Order vacating its Markman ruling. [D.I. 11 at Ex. A].

Impax has not explained, and would be hard-pressed to explain, how a vacated Markman ruling, or settlement of a prior lawsuit, could bind Wyeth to a claim construction that it vigorously contested and that is erroneous, or place any other possible restriction on Wyeth's recourse against infringers like Impax that could support an allegation of patent misuse. In essence, Impax's entire bad faith allegation is premised on converting a vacated Markman ruling into a disguised collateral estoppel on claim construction.

But it is black letter law that a vacatur, by definition, renders a court action of no legal moment. *See United States v. Munsingwear, Inc.*, 340 U.S. 36, 39-40 (1950) (stating that vacatur "clears the path for future relitigation of the issues between the parties and eliminates a judgment . . . . When that procedure is followed, the rights of all parties are preserved; none is prejudiced by a decision which in the statutory scheme was only preliminary."). Moreover, a Markman ruling itself does not have preclusive effect because it is interlocutory, and is likely to get reversed some 40% of the time on appeal after final judgment on infringement and/or validity. For example, in commenting on the interlocutory nature of Markman rulings, one court pointed out that:

> Disturbingly, although the Federal Circuit generally declines interlocutory appeals, when the court dismisses the claim or when parties battle the patent dispute to trial and then appeal the court's claim interpretation, "nearly 40 percent of claim constructions are changed or overturned by the Federal Circuit."

Kollmorgen Corp. v. Yaskawa Elec. Corp., 147 F. Supp. 2d 464, 467 (W.D. Va. 2001), *appeal dismissed*, 33 Fed. Appx. 496 (Fed. Cir. 2002) (internal citations omitted). Therefore,

> As more than forty percent of all *Markman* Orders are reversed by the Federal Circuit, logic dictates that for these claim constructions to have a preclusive effect, the litigants must first have an opportunity to seek Federal Circuit review. Parties to a settlement will lack any incentive to settle if the virtually unreviewable Markman ruling will have a preclusive effect on other potential patent actions.

Id. at 468.

Furthermore, a Markman ruling does not address infringement, whether literal or under the doctrine of equivalents. This further underscores the lack of finality in Markman rulings and thus the unlikelihood that a vacated Markman ruling would have a

preclusive effect in later litigation concerning different products. As the Federal Circuit pointed out in *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700 (Fed. Cir. 1983):

> Except in the context of validity or infringement, judicial statements regarding the scope of patent claims are hypothetical insofar as they purport to resolve the question of whether prior art or products not before the court would, respectively, anticipate or infringe the patent claims.

713 F.2d at 704. Accordingly,

> In view of the foregoing, we hold that judicial statements regarding the scope of patent claims are entitled to collateral estoppel effect in a subsequent infringement suit only to the extent that determination of scope was essential to a final judgment on the question of validity or infringement; further, that such statements should be narrowly construed.

Id. The Federal Circuit subsequently applied these principles in *Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1539 (Fed. Cir. 1995) ("The New Jersey court's finding of noninfringement of the '028 patent . . . did not meet the criteria for collateral estoppel, for the finding was not essential to the final judgment."). The district court in *Kollmorgen* similarly concluded that collateral estoppel does not apply because "the [prior] Wisconsin Court never reached a decision as to the patent infringement claim, the order necessarily could not prove essential to a non-existent final judgment. . . ." *Kollmorgen*, 147 F. Supp. 2d at 469-70. Wyeth's prior litigation settled before the district court made any rulings on validity or infringement, thus further underscoring that a vacated Markman ruling is of no legal moment to the correct meaning of the claims or how they apply to particular products.

In attempting to draw an inference from the timing of settlement based on an incorrect characterization of that timing, Impax merely casts unwarranted aspersions upon a settlement entered into willingly by the parties and approved by the New Jersey

district court. Impax ignores the fact that the law strongly encourages settlements, especially in patent litigation. As the court noted in *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368 (6th Cir. 1976),

> Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. . . . An amicable compromise provides the more speedy and reasonable remedy for the dispute.

531 F.2d at 1372 (*citing D. H. Overmeyer Co. v. Loflin*, 440 F.2d 1213 (5th Cir. 1971)); *accord Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988) (*citing Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976)); *see also Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) (*citing Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 349-50 (Fed. Cir. 1988)). Wyeth's settlement of previous litigation with a different party cannot reasonably support Impax's allegations as to what Wyeth "knows" about its own claims and the infringement of those claims by Impax.

Finally, although this is neither the time nor place to address claim construction, the Markman ruling also provides no evidence about what Wyeth "knows" the claims require (Opp., D.I. 14, at 11) because the Markman ruling was erroneous. The numerous errors in the ruling include reading into claims ingredients that were not recited in those claims, discounting the doctrine of claim differentiation, ignoring the ordinary meaning of the broad claim term "extended release formulation," misinterpreting the patent specification as giving a definition to the term "extended release formulation" that differs from its ordinary meaning, and giving no weight to unambiguous prosecution history that directly supports giving "extended release formulation" its ordinary meaning. Just some of these errors will be briefly addressed below.

D. Impax Mischaracterizes Wyeth's Patent Specification and Claims and Ignores Clear Errors in the New Jersey Court's Markman Ruling

Although claim construction is not at issue in Wyeth's motion, Impax seeks to convert its Opposition into a claim construction brief. But Impax's claim construction suffers from the same legal errors as the now vacated New Jersey Markman ruling. Impax dubiously assumes that all of the claims in the patents-in-suit necessarily require MCC and that any drug formulation not containing MCC could not possibly infringe the claims, even though:

- the patents-in-suit broadly disclose methods that are not dependent on MCC;
- several method claims do not even mention MCC;
- under the doctrine of claim differentiation, several independent method claims necessarily do not require MCC; and
- substantially equivalent substitutes for MCC allow one of ordinary skill in the art to practice Wyeth's invention using alternative embodiments that do not include MCC.

Impax's claim of patent misuse blithely hearkens to a legal nullity and error while ignoring the plain language of the claims and basic principles of claim construction.

1. Impax Ignores the Broad "Use" Aspect of Wyeth's Invention

Through selective quotation, Impax argues that the specifications of the patents-in-suit narrowly define the claim term "extended release formulation" as including MCC. (Opp., D.I. 14, at 5.) This is plainly incorrect. What Impax quotes is merely a discussion of an embodiment of the disclosed inventions, not a definition of the claim term "extended release formulation." Moreover, Impax's selective quotation fails to acknowledge the "use" aspect of Wyeth's invention, which is disclosed and claimed quite

broadly. Indeed, when the patent specification describes Wyeth's therapeutic methods, they do not limit the invention to a particular formulation. Rather, the patents-in-suit describe Wyeth's therapeutic methods without any mention of specific ingredients, other than the active ingredient venlafaxine hydrochloride. For example:

> *[I]n accordance with the use aspect of this invention*, there is provided a method for moderating the plural blood plasma peaks and valleys attending the pharmacokinetic utilization of multiple daily tablet dosing with venlafaxine hydrochloride which comprises *administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride*.

'171 patent col. 2, ll. 39-45 (emphasis added) (D.I. 1, Ex. A).

Impax then quotes claim 1 of the '171 patent, and alleges that "almost every claim of the patents-in-suit either explicitly requires [MCC] or depends from a claim explicitly requiring [MCC]. For example, in the '171 patent, the first 19 out of 25 claims explicitly require [MCC] or depend from a claim containing [MCC]." (Opp., D.I. 14, at 5-6). Impax conveniently fails to quote the several independent method claims of the '171 patent, which are directed to the "use" aspect of Wyeth's invention and which make no mention of MCC. For example, claim 20 of the '171 patent reads:

> A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period
>
> with diminished incidences of nausea and emesis
>
> which comprises administering orally to a patient in need thereof,
>
> an encapsulated, *extended release formulation*
>
> that provides a peak blood plasma level of venlafaxine in from about four to about eight hours,
>
> *said formulation containing venlafaxine hydrochloride as the active ingredient.* (emphasis added).

In stark contrast to claim 1 of the '171 patent which Impax quotes (Opp., D.I. 14, at 6), claim 20 does not limit the particular ingredients used in the "extended release formulation" employed in the method, except that the formulation must contain venlafaxine hydrochloride as the active ingredient. Impax cannot allege that Wyeth filed this lawsuit in bad faith simply because Wyeth refuses to adopt Impax's facially flawed claim construction which reads an element into claim 20 that is not there.[3]

2. The Doctrine of Claim Differentiation Underscores the Breadth of Wyeth's Independent Method Claims

Wyeth's independent claims to therapeutic methods also are not limited to specific ingredients, among other reasons, because specific ingredients for "extended release formulations" are expressly recited in dependent claims, but are absent from the independent claims. For example, claim 1 of the '120 patent (D.I. 1, Ex. B) (which contains the same specification as the '171 patent, discussed above) recites:

> A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period
>
> with diminished incidence of nausea and emesis
>
> which comprises administering orally to a patient in need thereof,
>
> an *extended release formulation*
>
> that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml,
>
> *said formulation containing venlafaxine hydrochloride as the active ingredient.* (emphasis added).

[3] Each of the three patents-in-suit contains independent method claims that similarly do not recite MCC.

In contrast, dependent claim 3 of the '120 patent recites "[t]he method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose." If, as Impax suggests, the term "extended release formulation" of claim 1 requires a formulation containing, *inter alia*, MCC, not only would this impermissibly read a particular embodiment from the specification into the claims, it would also render all of the above-underscored language of claim 3 of the '120 patent superfluous.

As the Federal Circuit acknowledged in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 1332 (2006), "claim differentiation" gives rise to a presumption that the limitations recited in other claims should not be read into claims that do not recite those limitations. In *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), which the *Phillips* court cited in its claim differentiation discussion, "the dependent claims differ[ed] from the independent claims only with regard to the presence of a pressure jacket in the dependent claims." 358 F.3d at 910. In such a case, the Court ruled that "the doctrine of claim differentiation is at its strongest," explaining:

> The juxtaposition of independent claims lacking any reference to a pressure jacket with dependent claims that add a pressure jacket limitation *provides strong support* for Liebel's argument that the independent claims were not intended to require the presence of a pressure jacket.

Id. (emphasis added). So too, here, the presence of dependent claims containing specific ingredients underscores the absence of those ingredients from Wyeth's independent method claims. Impax cannot claim that Wyeth filed this lawsuit in bad faith simply

because Wyeth refuses to adopt a claim construction that violates even the most basic tenets of claim construction.

E. Impax Cannot State a Counterclaim or Affirmative Defense of Patent Misuse as a Matter of Law, and Therefore Its Request For Leave to Amend Should Be Denied as Futile

Impax should not be permitted leave to amend because Impax cannot state a claim for patent misuse as a matter of law, and thus, any amendment would be futile.

Rule 15(a) of the Federal Rules of Civil Procedure permits amendment to pleadings, but "this liberal policy of granting leave to amend must not be interpreted to permit amendment without restraint." *Site Microsurgical Sys., Inc. v. Cooper Cos.*, 797 F. Supp. 333, 336 (D. Del. 1992). Indeed, an amendment should not be permitted if countervailing considerations such as undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice, or futility, exist. *Id.* (*citing Foman v. Davis*, 371 U.S. 178, 182 (1962)). Moreover, "[i]f the court determines that an amendment is clearly futile, leave to amend may be denied solely on that basis." *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 736 (D. Del. 2002); *see also Cowell v. Palmer Twp.* 263 F.3d 286, 296 (3d Cir. 2001). This Court has also acknowledged that it may clearly "deny a party leave to amend a complaint, or even grant a motion to strike, based on futility. . . ." *Agere*, 190 F. Supp. 2d at 736.

An amendment is considered futile if it cannot withstand a motion to dismiss. *Site Microsurgical Sys.*, 797 F. Supp. at 336; *Satellite Fin. Planning Corp. v. First Nat'l Bank of Wilmington*, 646 F. Supp. 118, 120 (D. Del. 1986). Thus, a claim may be dismissed or stricken if the moving party can show beyond doubt that the plaintiff or counterclaimant can prove no set of facts to support his claim that would entitle him to

relief. *Agere*, 190 F. Supp. 2d at 736; *Site Microsurgical Sys.*, 797 F. Supp. at 336. That is the case here.

The Federal Circuit has noted that "the defense of patent misuse may not be converted to an affirmative claim for damages simply by restyling it as a declaratory judgment counterclaim." *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1428 (Fed. Cir. 1997). District courts have followed this proposition of law. In *Depuy, Inc. v. Zimmer Holdings, Inc.*, 343 F. Supp. 2d 675, 684 n.4 (N.D. Ill. 2004), for example, citing *Braun*, the court noted that "patent misuse is an affirmative defense, not a counterclaim." Indeed, courts have relied on *Braun* to dismiss counterclaims for patent misuse on this basis alone. *See, e.g., PSN Illinois, Inc. v. Ivoclar Vivadent, Inc.*, No. 04 C 7232, 2005 WL 2347209, at *3 (N.D. Ill. Sept. 21, 2005); *Bernhardt L.L.C. v. Collezione Europa USA, Inc.*, No. Civ. 101CV00957, 2002 WL 1602447, at *2 (M.D.N.C. July 3, 2002).

In the *Depuy* case, the defendant alleged patent misuse on the basis that the plaintiff had settled prior litigation by granting licenses to defendants who had placed the validity of Depuy's patent in issue. *Depuy*, 343 F. Supp. 2d at 685. The defendant argued that the granting of the licenses after validity had been placed in issue somehow amounted to an admission of invalidity by the plaintiff patentee. *Id.* Citing 35 U.S.C. § 271(d), the court refused to permit an inference of patent misuse, and struck the defendant's affirmative defense. *Id*. It is similarly impermissible to infer misconduct by Wyeth here. As discussed above, Impax's sole basis for asserting patent misuse is that Wyeth purportedly "knows" that its claims require MCC, and it knows that Impax's formulation does not contain MCC. But Impax's sole basis for arguing what Wyeth

"knows" about what Wyeth's claims "require" is a vacated, erroneous Markman ruling in a settled prior litigation.

For the reasons presented above, Impax's argument is entirely misplaced, and provides no basis at all for an allegation of patent misuse. Nothing can be gained from allowing Impax to amend its pleading, as Impax has not provided any grounds in its Opposition that it could add to its pleading that would rescue its new patent misuse allegations. Accordingly, Impax's unenforceability defenses and counterclaims should be dismissed with prejudice.

CONCLUSION

For the foregoing reasons, Wyeth's motion to strike Impax's unenforceability/ unclean hands defenses and to dismiss its unenforceability counterclaims should be granted.

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP

/s/ *Karen Jacobs Louden*

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
klouden@mnat.com
Chase Manhattan Centre, 18th Floor
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Plaintiff Wyeth

OF COUNSEL:
Basil J. Lewris, Esq.
Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

June 8, 2006

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on June 8, 2006 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on June 8, 2006 upon the following in the manner indicated:

BY HAND

Mary B. Matterer
Morris, James, Hitchens & Williams
222 Delaware Avenue
P.O. Box 2306
Wilmington, DE 19899

BY FEDERAL EXPRESS

M. Patricia Thayer
John M. Benassi
Jessica R. Wolf
Heller Ehrman LLP
4350 La Jolla Village Dr.
San Diego, CA 92102

/s/ Karen Jacobs Louden
Karen Jacobs Louden (#2881)
klouden@mnat.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRISTRATA TECHNOLOGY, INC.,	:	
Plaintiff,	:	
v.	:	Civil Action No. 96-227-JJF
NEOTERIC COSMETICS, INC., MURAD SKIN RESEARCH LABORATORIES, INC., HOWARD MURDAD, M.D., ERNO LASZLO DIVISION, CHANEL, INC. and CLARINS USA, INC., COSMAIR, INC.	:	
Defendants.	:	

Thomas J. Allingham, II, Esquire and Robert S. Saunders, Esquire of SKADDEN, ARPS, SLATE, MEAGHER & FLOM, Wilmington, Delaware. Of Counsel: Constance S. Huttner, Esquire and John L. Gardiner, Esquire of SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP, New York, New York; Kevin M. McGovern, Esquire and Brian T. Foley, Esquire of McGOVERN & ASSOCIATES, Greenwich, Connecticut. Attorneys for Plaintiff.

Allen M. Terrell, Jr., Esquire and Frederick L. Cottrell, III, Esquire of RICHARDS, LAYTON & FINGER, Wilmington, Delaware. Of Counsel: David Wolf, Esquire, Stanley Sacks, Esquire and Robert E. Rigby, Jr., Esquire of WOLF, GREENFIELD & SACKS, P.C. Attorneys for Defendant Neoteric Cosmetics, Inc.

Jack B. Blumenfeld, Esquire, Thomas C. Grimm, Esquire, Matthew B. Lehr, Esquire and Maryellen Noreika, Esquire of MORRIS, NICHOLS, ARSHT & TUNNELL, Wilmington, Delaware. Attorneys for Defendants Murad Skin Research Laboratories, Inc. and Howard Murad, M.D.

James F. Burnett, Esquire and Joanne Ceballos, Esquire of POTTER ANDERSON & CORROON, Wilmington, Delaware. Of Counsel: Yosef J. Riemer, Esquire and Sarah Slover, Esquire of KIRKLAND & ELLIS, New York, New York; Robert P. Oppenheim, Esquire of COBLENCE & WARNER, New York, New York; Paul H. Heller, Esquire, Albert J. Breneisen, Esquire and Daniel F. Coughlin, Esquire of KENYON & KENYON, New York, New York. Attorneys for Defendant Chanel, Inc. and Clarins USA, Inc.

Kent A. Jordan, Esquire of MORRIS, JAMES, HITCHENS & WILLIAMS, Wilmington, Delaware. Of Counsel: Richard D. Kelly, Esquire and Jean-Paul Lavalleye, Esquire of OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C., Arlington, Virginia. Attorneys for Defendant Cosmair, Inc.

MEMORANDUM OPINION

September 30, 1997

Wilmington, Delaware

Farnan, Chief Judge.

Presently before the Court is a Motion For Judgement Dismissing Neoteric's Counterclaim For Patent Misuse Pursuant To Fed. R. Civ. P. 12(c) (D.I. 77) filed by Plaintiff TriStrata Technology, Inc. ("TriStrata"). In its Answer to the Complaint, Neoteric sets forth a two count Counterclaim. Count I alleges that the patents in issue are invalid and/or unenforceable, and Count II alleges breach of contract against TriStrata. Pursuant to a stipulation (D.I. 76), Neoteric dismissed Count II of its Counterclaim without prejudice. Subsequently, TriStrata filed the instant motion seeking dismissal of the remainder of the Counterclaim. For the reasons set forth below, the Court will grant TriStrata's motion. However, the Court will also grant Neoteric leave to file an Amended Counterclaim.

BACKGROUND

The instant motion arises in the context of a patent infringement action brought by TriStrata against Neoteric and others. The patents in issue (the "AHA Patents") describe and claim a method of using a composition containing an "alpha-hydroxy acid" ("AHA"), such as glycolic or lactic acid, to treat and/or reduce the appearance of wrinkles and/or fine lines on human skin. The AHA Patents were originally issued to Drs.

Eugene J. Van Scott and Ruey J. Yu, and subsequently were assigned to TriStrata. In its Complaint, TriStrata alleges that Neoteric and others willfully and deliberately infringed the AHA patents.

In addition to answering the Complaint, Neoteric filed a two-count Counterclaim against TriStrata. By stipulation, Neoteric dismissed Count II of the Counterclaim. The remaining Count consists of three paragraphs numbered 59-61. Paragraph 60 alleges that the AHA Patents "are invalid and unenforceable under the Patent Laws of the United States, including 35 U.S.C. § 101, 102, 103 and 112; and by reason of obviousness-type double patenting." In the instant motion, TriStrata expressly states that it does not seek dismissal of the allegations contained in paragraph 60. (D.I. 78 at 3, n.4). However, TriStrata does seek dismissal of the allegations contained in paragraph 61 of the Counterclaim. Paragraph 61 alleges that the AHA Patents are

> void and unenforceable because plaintiff has misused its patents by virtue of asserting claims against other including Neoteric and, on information and belief, by entering into agreements, which claims and agreements purport coverage of the [AHA patents], which plaintiff knows or should know are beyond the metes and bounds of the [AHA patents] as defined by the claims thereof. As part of said misuse, plaintiff has embarked upon a calculated scheme knowingly intended to achieve a monopoly in the manufacture, sale and use of skin cosmetics containing alpha hydroxy acids and, in

> particular, glycolic acid. Such misuse has in part been attempted through seeking and obtaining numerous patents having overlapping claims and non-coextensive termination dates, said patents being patentably indistinct from one another by engaging in predatory licensing and threats and through the use of extensive and misleading representations to the Patent Office.

(D.I. 20 at 12).

STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 12(c), "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." In deciding a motion to dismiss on the pleadings, courts utilize the same legal standard that applies to Rule 12(b)(6) motions. See Finch v. Hercules, Inc., 809 F. Supp. 309, 310 (D. Del. 1992) (citations omitted). As such, a court must accept as true all factual allegations in the claim and must draw all reasonable factual inferences in the light most favorable to the non-moving party. However, a court "need not accept any conclusory allegations or statements of law." In re General Motors Class E Stock Buyout Sec. Litig., 694 F. Supp. 1119, 1125 (D. Del. 1988). Dismissal of a claim is only appropriate when it appears beyond doubt that the plaintiff can prove no set of facts entitling him to relief. Revis v. Slocomb, 765 F. Supp. 1212, 1213 (D. Del. 1991). In applying this standard, the moving party bears the

burden of showing that dismissal is warranted. See Finch, 809 F. Supp. at 310.

DISCUSSION

In its motion, TriStrata seeks to dismiss the patent misuse allegation contained in paragraph 61 of the Counterclaim. In particular, TriStrata contends that: (1) its patent enforcement and licensing activities cannot constitute patent misuse under the "Safe Harbor" Provisions of 35 U.S.C. § 271(d); (2) Neoteric's allegation that TriStata committed fraud on the patent office is inadequately pled, (3) Neoteric's allegation that TriStrata "knowingly intended to achieve a monopoly in the manufacture, sale and use of skin cosmetics containing AHA, and in particular glycolic acid" fails to state a claim for relief, and (4) Neoteric's allegation that Tristrata entered into agreements which it knew or should have known extended beyond the metes and bounds of the patent fails to state a claim for relief.

In response, Neoteric asserts four arguments. First, Neoteric contends that its allegations are sufficient to support its Counterclaim for patent misuse. Second, Neoteric contends that TriStrata's motion cannot carry its burden on the motion. Third, Neoteric contends that TriStrata's motion is premature. And, fourth, Neoteric contends that if the Court concludes that

its Counterclaim is not adequately pled, then the more appropriate remedy is a more definite statement.

A. Neoteric's Allegation That TriStrata Enforcement and Licensing Activities Amounted To Misuse

In seeking to dismiss Neoteric's Counterclaim for patent misuse, TriStrata contends that several allegations contained in paragraph 61 of the Counterclaim fall within the "safe harbor" provision of 35 U.S.C. § 271(d). Section 271(d) provides:

> No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent, (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement [or] (4) refused to license or use any rights to the patent, or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

35 U.S.C. § 271(d).

In response to this argument, Neoteric contends that Section 271(d) is inapplicable to the instant case, because "even if TriStrata's factual allegations as set forth in the Complaint

were true, and even if the patents were valid, Neoteric, at best, would only be liable for inducing infringement" and inducing infringement is not contemplated by the provisions of Section 271(d). While Neoteric admits that TriStrata has charged it with infringement, contributory infringement and inducing infringement, Neoteric contends that "it should be apparent from the pleadings" that it has neither infringed nor contributorily infringed. Further, Neoteric contends that pursuant to the standard of review under Rule 12(c), the Court must accept, as true, its allegation that it would only be liable for inducing infringement.

The Court is not persuaded by Neoteric's argument. First, under the applicable standard of review, the Court must accept the truth of Neoteric's factual allegations. Neoteric's assertion that it, at most, would be liable for inducing infringement and that it has neither infringed nor contributorily infringed are legal conclusions, the truth of which the Court is not required to accept for purposes of a Rule 12(c) dismissal. See e.g. In re General Motors, 694 F. Supp. at 1125. Moreover, at this stage of the proceedings, the Court is not prepared to address the legal merits of TriStrata's infringement claims. Therefore, the Court declines to accept Neoteric's contention

that it is apparent from the pleadings that it has neither infringed nor contributorily infringed.

Second, the Court declines to accept Neoteric's narrow interpretation of Section 271(d). Neoteric has not offered any authority to support its contention that Section 271(d) does not extend to protect claims of inducing infringement, and the Court has not been able to locate any support for that proposition. Indeed, the Supreme Court acknowledged in Dawson Chemical Co. v. Rohm & Haas Co., that Section 271(d) "moved in the direction of expanding the statutory protection enjoyed by patentees." 448 U.S. 176, 213, reh'd denied, 448 U.S. 917 (1980). By its express terms, Section 271(d) includes patent owners who are entitled to relief for infringement, as well as contributory infringement. Given the language of Section 271(b), which states that "[w]hoever actively induces infringement of a patent shall be liable as an infringer," the Court cannot say that the term "infringement" as used in Section 271(d) excludes inducing infringement. Therefore, even if Neoteric is correct that it is not liable for direct or contributory infringement, the Court cannot conclude that Section 271 would be inapplicable. See Dawson, 448 U.S. at 176 (holding conduct of patent holder, who sought to enforce patents under theories of both contributory and

induced infringement, protected under provisions of § 271(d)).

In examining Neoteric's allegations of patent misuse in light of the provisions of Section 271(d), the Court concludes that a number of Neoteric's allegations of patent misuse are within the safe harbor provisions of that section. Subsections (2) and (3) expressly encompass a patent owners license activities and enforcement activities. Indeed, in discussing Section 271(d), the Supreme Court stated that "[t]his provision plainly means that the patentee may bring suit without fear that doing so will be regarded as an unlawful attempt to suppress competition." See Dawson, 448 U.S. at 201. Thus, Neoteric's allegations that TriStrata misused its patents by "asserting claims against others including Neoteric," (2) "entering into agreements," and (3) engaging in "predatory licensing and threats" are licensing and enforcement activities that do not constitute misuse under Section 271(d). To the extent that Neoteric contends that certain licensing and enforcement activities were improper and thus, not within the protection of Section 271(d), the Court finds Neoteric's allegations to be insufficient and conclusory. Indeed, Neoteric has not alleged any facts that would lead the Court to conclude that TriStrata's activities fall outside the safe harbor provisions. Accordingly,

the Court will dismiss, with leave to amend, Neoterics's Counterclaim of misue based upon TriStrata's enforcement and licensing activities. See e.g. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 1996 WL 467273 at *6 (N.D. Cal. July 24, 1996) (striking misuse allegation where no factual basis provided for defendant's contention that patent owner knew patent was invalid, and nonetheless willfully, deliberately and intentionally asserted it against defendant).

B. Neoteric's Allegation that TriStrata Committed Fraud On The Patent Office

In its Counterclaim, Neoteric contends that TriStrata's misuse "has in part been attempted through seeking and obtaining numerous patents having overlapping claims and non-coextensive termination dates, said patents being patentably indistinct from one another . . . through the use of extensive and misleading representations to the Patent Office." To the extent that this claim alleges that TriStrata committed fraud on the Patent Office, the Court concludes that it is deficient as a matter of law.

Pursuant to Federal Rule of Civil Procedure 9(b) allegations of fraud must be pled with particularity. In its Counterclaim, Neoteric has not pled any specific facts to support its assertion

that TriStrata made extensive and misleading representations to the Patent Office. Rather, Neoteric appears to base its claim of fraud on its allegation that TriStrata has obtained patents with overlapping claims and non-coextensive termination dates, that are patentably indistinct from one another. While Neoteric provides facts relevant to this allegation in its brief, it does not offer those or any other facts to support this allegation in its pleadings.

Although Neoteric relies on Raychem Corp v. PSI for the proposition that it has provided TriStrata reasonable notice of the conduct which it alleges constitutes fraud, the Court believes that Raychem lends greater support for the Court's conclusion that Neoteric's misuse claim is inadequately pled. 1995 WL 108193 (N.D. Cal. 1995). In Raychem, the defendant based his defense of patent misuse on assertions of "inequitable conduct," "mutually exclusive patents," and patents which "are clearly not capable of being properly construed to cover the accused infringing devices." In striking the defense of patent misuse and granting defendant leave to amend, the Raychem court concluded that the defendant has not offered a sufficient factual basis upon which to base its allegations. In this case, the Court finds Neoteric's conclusory allegation of "patents having

overlapping claims" to be similar to the conclusory allegations that the Raychem court found insufficient. Because the Court concludes that Neoteric's claims of patent misuse based on fraud on the Patent Office and overlapping patent claims are not sufficiently pled, the Court will grant TriStrata's motion to dismiss, but allow Neoteric the opportunity to amend its Counterclaim.

C. Neoteric's Allegation That TriStrata Knowingly Intended To Achieve A Monopoly

As another basis for its allegation of misuse, Neoteric contends that TriStrata "has embarked upon a calculated scheme knowingly intended to achieve a monopoly in the manufacture, sale and use of skin cosmetics containing alpha hydroxy acids, and in particular, glycolic acid." In its brief, Neoteric attempts to support this contention with the additional allegation that TriStrata "is targeting the entire AHA market, not just limited uses of AHA." As a factual basis for these assertions, Neoteric offers TriStrata's statement in its opening brief that "the market for AHA containing cosmetics products has exploded; it is currently estimated to be in excess of $800 million per year, and all indications are that it will continue to grow in the future." (D.I. 78 at 2).

As with Neoteric's other allegations, the Court concludes that Neoteric's Counterclaim of misuse based on attempted monopolization is inadequately pled. As a general principle, a patent holder is entitled to maintain a patent monopoly by excluding others from making using or selling the patented invention, as long as the patent owner's conduct is permissible under the patent laws. See SCM Corp. v. Xerox Corp, 645 F.2d 1195, 1204 (2d Cir. 1981), cert. denied, 455 U.S. 1016 (1982).

To the extent that Neoteric relies on TriStrata's statement concerning the "market for AHA containing cosmetics" as factual support for its Counterclaim, the Court finds the statement to be inadequate. Examined in context, TriStrata's statement is simply a background comment on the magnitude of the AHA market. As such, the Court declines to accept this statement, taken out of context, as sufficient factual support for a claim of misuse based on attempted monopolization. Therefore, the Court will grant TriStrata's motion to dismiss Neoteric's claim of patent misuse based on attempted monopolization, but will grant Neoteric the opportunity to amend.

D. Neoteric's Allegation That TriStrata Entered Into Agreements Which It Knew Or Should Have Known Extended Beyond The Metes And Bounds Of The Patent

Regarding Neoteric's allegation that TriStrata has engaged

in misuse by attempting to enforce its patents beyond their limits, the Court concludes that Neoteric has not offered sufficient factual support for its contention. Again, the Court believes this allegation resembles the conclusory type of allegation that the Raychem court found to be lacking factual support. In dismissing the defendant's allegation that the patents "are not capable of being properly construed to cover the accused infringing devices," the Raychem court stated that the defendant failed to "include any facts demonstrating how or why [the plaintiff] has attempted to overbroadly and impermissibly construe its patents in an anticompetitive fashion." 1995 WL 108193 at *4. Likewise, in this case, Neoteric has not offered any facts or examples demonstrating how TriStrata's agreements with others have extended beyond the scope of the patents. Therefore, the Court will grant TriStrata's motion to dismiss, but will grant Neoteric leave to amend its Counterclaim.

E. Whether TriStrata's Rule 12(c) Motion Is Premature

Neoteric contends that the Court should deny TriStrata's motion because it is untimely. According to Neoteric, the pleadings are not closed within the meaning of Rule 12(c), because TriStrata's Motion For Relief To File A Second Amended Complaint is pending.

Subsequent to the instant motions, the Court granted TriStrata leave to file its Second Amended Complaint and the Second Amended Complaint was filed. Thus, in the first instance, Neoteric's argument is moot.

However, even if it were not moot, the Court declines to accept Neoteric's argument that the pendency of an amended pleading prevents the pleadings from being considered closed. In its own research, the Court has been unable to locate any authority either in the Federal Rules of Civil Procedure or in the relevant case law to support this proposition. See e.g. Katz v. Aiwa Am. Inc., 818 F. Supp. 730, 735 n.3 (D.N.J. 1993) (concluding that pleadings were "closed" despite pending motion to amend counterclaims).

Moreover, according to Moore's Federal Practice, "[u]nless the court orders a reply to an answer or third-party answer, the pleadings close after the last of the following pleadings in the case has been filed: answer, reply to a counterclaim, answer to a cross-claim, and third-party answer." James Wm. Moore, et al. Moore's Federal Practice, ¶12.38 (3d ed. 1997). The Court notes that Moore's makes no mention of the effect of amended pleadings on this general rule of determining when pleadings close. Id.

In this case, TriStrata filed a Reply (D.I. 34) and Amended

Reply (D.I. 44) to Neoteric's Counterclaim before filing its Rule 12(c) motion. As such, the Court concludes that the pleadings are properly considered closed and TriStrata's motion pursuant to Rule 12(c) is not untimely.

CONCLUSION

For the reasons discussed, TriStrata's Motion For Judgement Dismissing Neoteric's Counterclaim For Patent Misuse Pursuant To Fed. R. Civ. P. 12(c) (D.I. 77) will be granted. However, the Court will grant Neoteric leave to amend its Counterclaim.[1]

An appropriate Order will be entered.

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[1] Although TriStrata contends that no amount of additional pleading could salvage Neoteric's patent misuse Counterclaim, the Court believes that its decision to permit Neoteric leave to amend is consistent with the approach of other courts that have dismissed or stricken allegations based on insufficient pleading. See e.g. Raychem, 1995 WL 108193 at *4-5.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRISTRATA TECHNOLOGY, INC., Plaintiffs,	:	
v.	:	Civil Action No. 96-227-JJF
NEOTERIC COSMETICS, INC., MURAD SKIN RESEARCH LABORATORIES, INC., HOWARD MURDAD, M.D., ERNO LASZLO DIVISION, CHANEL, INC. and CLARINS USA, INC., Defendants.	:	

O R D E R

At Wilmington this 30 day of September 1997, for the reasons set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. TriStrata's Motion For Judgment Dismissing Neoteric's Counterclaim For Patent Misuse Pursuant to Fed. R. Civ. P. 12(c) (D.I. 77) is GRANTED.

2. Neoteric is granted leave to file an Amended Counterclaim within 20 days of the date of this Order.

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No.: 03-1293 (WJM)

DISMISSAL ORDER

As a result of the parties having executed the Settlement and Release Agreement dated November 2, 2005 and the License Agreement (as defined in the Settlement and Release Agreement), the Court hereby Orders:

1) Until the expiration of United States Patent Nos. 6,274,171 B1; 6,403,120 B1; and 6,419,958 B2; or the termination of the License Agreement, Defendants shall not make, use, sell, offer for sale, or import XR Product, as that term is defined in the License Agreement, for use in the Territory, except as licensed under the License Agreement.

2) Defendants' Counterclaim(s) of patent invalidity and unenforceability are dismissed with prejudice. Defendants' Counterclaim(s) of non-infringement are dismissed without prejudice.

3) The Settlement and Release Agreement and the License Agreement entered into between the parties, which have been filed with this Court under seal, are adopted by the Court as part of this Order.

4) This Court retains jurisdiction to enforce this Order and the parties' Settlement and Release Agreement and License Agreement.

SO ORDERED.

William J. Martini, U.S.D.J.

Jan 12, 2006